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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|----------------------------|----------------------|---------------------|------------------|
| 10/587,370 | 05/29/2007 | Robert F. Kelley | 50474/007002 | 1889 |
| 21559 CLARK & ELI | 7590 05/30/200 BING LLP | 8 | EXAMINER | |
| 101 FEDERAL BOSTON, MA | STREET | | STOICA, ELLY GERALD | |
| bos ion, ma | 02110 | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | | |
| | | | 05/30/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

| | Application No. | Applicant(s) | | | | |
|--|--|-------------------------------|-----------|--|--|--|
| Office Action Comments | 10/587,370 | KELLEY ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | ELLY-GERALD STOICA | 1647 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence addi | ress | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | | | | | | |
| | -· action is non-final. | | | | | |
| ·— | | secution as to the r | merits is | | | |
| • | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| ciocoa in accordance mantino praesico anaci | A parte dadyre, 1000 0.2. 11, 10 | 0.0.2.0. | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-50</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdray | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)☐ Claim(s) is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) <u>1-50</u> are subject to restriction and/or e | election requirement. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examine | r. | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of | s have been received. s have been received in Application ity documents have been received (PCT Rule 17.2(a)). | on No d in this National S | tage | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | te | | | | |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-7, 12, 14, 16, 17 (in part), 18, 19, 23-29, and 33-34, drawn to a polypeptide that binds APRIL.

Group II, claims 8-11, 13, 15, 17 (in part) and 20-22 drawn to a polypeptide that binds BAFF.

Group III, claims 30-32 and 35, drawn to a nucleic acid that encodes for a polypeptide that binds APRIL.

Group IV, claims 36, 38, 40 (in part), 41, and 43 (in part) drawn to a method of identification of an APRIL binding inhibitor.

Group V, claims 37, 39, 40 (in part), drawn to a method of identification of a BAFF binding inhibitor.

Group VI, claims 44-45, drawn to a method of treatment of an immune-related disease. Group VII, claims 46-48, drawn to a method of treatment for cancer.

Group VIII, claims 49-50, drawn to a method of treatment of a T-cell mediated disease.

2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: The groups of

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inventions as set out above relate to variants of the cysteine rich domain of BCMA. The

two groups do NOT share a common structural feature which is novel over the parent

molecule, namely the CRD of BCMA itself. Moreover, the variants of the first two groups

have different functionalities. Variants belonging to the first group have retained or

enhanced APRIL binding capacities, variants belonging to the second group have

retained or enhanced BAFF binding capacities.

3. This application contains claims directed to more than one category of species of

the generic invention. These species are deemed to lack unity of invention because

they are not so linked as to form a single general inventive concept under PCT Rule

13.1.

The categories species are as follows:

A) amino acid sequences

B) diseases

Applicant is required, in reply to this action, to elect a single ultimate species

from each category to which the claims shall be restricted if no generic claim is finally

held to be allowable. In order to be considered fully responsive, for the category A)

Applicant must choose a single defined sequence (i.e. with all the amino acids spelled

out) identified by a Seq. Id. No. or a sequence that contains one variable amino acid

residue (such as Xaa), also identified by a Seq. Id. No. The reply must also identify the

claims readable on the elected species, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Category A) claims 1-50; category B)-claims 44-50

The following claims are generic: 1, 8, 44, 47 and 49.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they have different structures and different biochemical properties.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

- 6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

 All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result

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in a loss of the right to rejoinder. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement

is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to ELLY-GERALD STOICA whose telephone number is

(571)272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone

number for the organization where this application or proceeding is assigned is 571-

273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine_Spector/, Ph.D.

Primary Examiner, Art Unit 1647